REMARKS

Rejection of Claims and Traversal Thereof

In the September 23, 2003 Office Action,

claims 1-11 and 13-15 were rejected under 35 U.S.C. §112, first paragraph.

This rejection is hereby traversed and reconsideration of the patentability of the amended claims is therefore requested in light of the following remarks.

Rejection under 35 U.S.C. § 112, first paragraph

In the September 23, 2003 Office Action, claims 1-11 and 13-15 were rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains or with which it is most nearly connected, to make and/or use the invention.

According to the Office, the disclosure is enabling for:

> "a method for lowering chemotherapy resistance in a patient being treated with a chemotherapeutic agent for a small cell lung cancer or pancreatic cancer, the method comprising administering an effective amount of AAV-2 intratumorally in combination of a chemotherapeutic agent to the patient; and determine whether the chemotherapeutic resistance to the chemotherapeutic agent is lowered; a pharmaceutical composition containing a chemotherapeutic agent and an effective dose of AAV-2 to lower resistance of tumor cells to said chemotherapeutic agent in a patient suffering from a small cell lung cancer or pancreatic cancer when it is administered intratumorally; a method for enhancing chemosensitivity of tumor cells to a chemotherapeutic agent, the method comprising administering a sufficient amount of AAV-2 intratumorally in combination with said chemotherapeutic agent, and determine whether the tumor growth is reduced, wherein the tumor cells are selected from small cell lung cancer or pancreatic caner;"

Applicants have amended the pending claims to recite the compositions and methods found to be enabling by the Office. Accordingly applicants request that all rejections under 35 U.S.C. §112, first paragraph be withdrawn.

CONCLUSION

The pending claims 1-3, 6-11 and 13-14, as now amended, meet all disclosure requirements and patentably distinguish over the prior art, and in view of the forgoing remarks, it is respectfully requested that all rejections be withdrawn, thereby placing the application in condition for allowance. Notice of the same is earnestly solicited. In the event that any issues remain, Examiner Qian is requested to contact the undersigned attorney at (919) 419-9350 to resolve same.

Respectfully submitted,

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In the Claims

1) (Currently amended) A method for lowering chemotherapy- resistance in a patient being treated with a chemotherapeutic agent for a small cell lung or pancreatic cancer, the method comprising:

administering to ~~infecting~~ the patient ~~with~~ an effective amount of AAV-2 to lower the chemotherapy resistance to the chemotherapeutic agent, in combination with administering a chemotherapeutic agent, wherein the effective amount of AAV-2 is administered intratumorally; and

determining if the chemotherapy resistance to the chemotherapeutic agent is lowered.

2) (Previously presented) The method according to claim 1, wherein the AAV-2 is used in a dose of 10^9 - 10^{10} AAV particles/kg body weight.

3) (Previously presented) The method according to claim 1 wherein the chemotherapeutic agent is selected from the group consisting of: cisplatin, etoposide and cisplatin/etoposide.

4) (Currently canceled)

5) (Currently canceled)

6) (Currently amended) The method according to claim 1 ~~any of claims 1 to 5~~, wherein the ~~infecting with~~ the AAV-2 is administered ~~made~~ before, after or simultaneously with a chemotherapy treatment.

7) (Currently amended) A pharmaceutical composition containing a chemotherapeutic agent and an effective dose of AAV-2 to lower resistance of tumor cells to the chemotherapeutic agent ~~reverse chemotherapy-induced resistance~~ in patients suffering from a cancer selected from the group consisting of ~~colon cancer~~, pancreatic carcinoma, ~~brain tumor~~ and small cell lung carcinoma, wherein the pharmaceutical composition is administered intratumorally.

8) (Previously presented) The pharmaceutical composition according to claim 7, wherein the chemotherapeutic agent is selected from the group consisting of: cisplatin, etoposide and cisplatin/etoposide.

9) (Currently amended) The pharmaceutical composition according to claim 7 or 8, wherein the composition is formulated in ~~a member selected from the group consisting of;~~ an injection solution, ~~infusion solution, an aerosol spray or an ointment~~.

10) (Currently amended) A method for reducing resistance to a chemotherapeutic agent in a patient suffering from a chemotherapy drug resistant small lung carcinoma or pancreatic cancer and treated for the cancer by a chemotherapeutic agent selected from the group consisting of cisplatin, etoposide and cisplatin/etoposide, the method comprising:

administering intratumorally to ~~infecting~~ the patient ~~with~~ a sufficient amount of AAV-2 to reduce resistance to the chemotherapeutic agent, in combination with administering the chemotherapeutic agent to the patient; and

determining if resistance to the chemotherapeutic agent is reduced.

11) (Previously presented) The method according to claim 10, wherein the AAV-2 is administered at a dose of 10^9 - 10^{10} AAV particles/kg body weight.

12) Cancelled

13) (Currently amended) A method for enhancing chemosensitivity of cancer tumor cells to a chemotherapeutic agent to reduce tumor growth, the method comprising:

administering ~~infecting the cancer cells with~~ a sufficient amount of AAV-2 intratumorally to enhance chemosensitivity of the cancer tumor cells to the chemotherapeutic agent, in combination with administering the chemotherapeutic agent to the cancer cells, and

determining if tumor growth is reduced, whereby a reduction in tumor growth indicates the chemosensitivity of cancer tumor cells is enhanced and wherein the tumor cells are selected from small cell lung cancer or pancreatic cancer.

14) (Previously presented) The method according to claim 13, wherein the chemotherapeutic agent comprises an agent selected from the group consisting of: cisplatin, etoposide and cisplatin/etoposide.

15) (Currently canceled)